UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,674	11/01/2006	Reza Eivaskhani	CCS-5001-USPCT1	3640

27777 7590 05/28/2008

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
DICKINSON, PAUL W	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,674	EIVASKHANI ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. None of the moisture sensitive active ingredients meet the written description provision of 35 USC § 112, first paragraph, due to lacking representative examples for what they are. Moisture sensitive active ingredients constitute a genus that is highly variant and encompasses a myriad of possibilities. The specification provides insufficient written description to support this genus, since there is only one representative example (topiramate) and no reasonable guidance provided that would allow one of skill in the art to determine what compounds are encompassed by this genus.

The appearance of mere indistinct words (here the word “inhibitor”) in a specification or a claim, even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material

does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). No such correlation has been disclosed here; at best all that can be inferred from the instant specification is that compounds having the general formulae set forth at page 5 of the specification inhibit the production of downstream products of 14 kD PLA2, such as arachidonic acid. See the first paragraph on page 13. Whether this was specifically due to inhibition of enzyme activity, or also due inhibition of production, transcription or translation, or some combination of these, is not clear from the data presented.

The examiner recognizes that the fact situation in the Rochester cases was extreme, with Applicant disclosing there no (or possibly one) specific compounds. The reasoning provided by the court can be fairly extended to less extreme situations (*i.e.*, where a limited number of species is actually disclosed, such as here), however, given the court's recognition that:

> [I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. Rochester (2003) at 1431.

As was the case in Rochester, there is no such specificity here, nor could one

skilled in the art identify any particular compound, other than those having the general formula set forth at the top of page 5 of the specification, as being able to inhibit any particular mechanism of 14 kDa PLA_2 action, other than to inhibit its "activity" in some unspecified way.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "if... desired" in Claims 12 and 13 renders each claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9944581 (hereafter WO '581; document provided by Applicant). WO '581 discloses bi-phasic tablets comprising an effective amount of topirmate, present in a core phase, and wherein the core is coated with a phase comprising povidone (a hygroscopic gum material) (see page 5, line 28 to page 10, line 11; Table 3; Examples

1-3; Claims 1, 10-11). The povidone is present in approximately 33% by weight relative to the total coating phase (calculcated using Table 3: (6.489 povidone/(6.489 povidone + 12.051 Cellulose Acetate)). The (pre-shaped) core phase and (pre-shaped) coating phase is then compressed in an appropriate compressing apparatus (see page 7, line 26 to page 8, line 2; see page 6, line 31 to page 7, line 2; Example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9944581 (hereafter WO '581; document provided by Applicant). As stated above, WO '581 discloses bi-phasic tablets comprising an effective amount of topirmate, present in a core phase, and wherein the core is coated with a phase comprising povidone (a hygroscopic gum material). The povidone is present in approximately 33% by weight relative to the total coating phase. In addition, the reference teaches using alginic acid (alginate) as a substitute for povidone in the coating phase (see page 9, line 14; Claim 21). The core phase may be compressed prior to adding the coating phase (see page 7, line 26 to page 8, line 2). The bi-phasic tablets are useful for treating epilepsy (see abstract).

WO '581 fails to disclose a specific combination or example with a core phase comprising alginate. WO '581 further fails to disclose a specific example wherein the core phase is compressed prior to adding the coating phase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose alginate as a component in the core phase, with a reasonable expectation of success, as this selection is taught by WO '581 as an embodiment that provides topiramate formulations useful for treating epilepsy. It would be further obvious to compress the core phase before adding the coating phase, as this is a disclosed embodiment of the invention that provides topirimate formulations useful for treating epilepsy.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050158385 (hereafter '385). '385 discloses multi-layered tablets comprising three layers, namely, a core, a middle layer, and an outershell, wherein an effective amount of a pharmaceutically active compound is present in any one of the three layers, and a thermoplastic polymer may be present in any one of the three layers, and the pharmaceutical active compound and thermoplastic polymer may be in different layers (see abstract; ¶1, 9-10, 16-23; Figure 2; Claims 1, 8, 10, 12, and 15). The outershell of '385 corresponds to the coating as disclosed in Instant Claims 9-10. An exemplified pharmaceutically active compound is 2,3:4,5-bis-O-(1-methylethyldiene)-beta-D-fructopyranose sulfamate (topiramate) (see ¶ 37; Example 3). Preferred thermoplastic polymers include hydroxypropyl methylcellulose and xanthan gum (see ¶ 23; Claim 15). The core is compressed before adding the other layers with a single screw extruder (see Example 1). The multi-layered tablets are compressed by using an embedded cutting roll (see Examples 1-3). The multi-layered tablets have several advantages over other tablet formulations, including tunable dosage strength (see abstract; ¶ 9-10)

'385 fails to disclose a specific combination or example of a multi-layered tablet comprising topiramate and xanthan gum.

It would be obvious to one of ordinary skill in the art at the time the invention was made to prepare a multi-layered tablet comprising topiramate and xanthan gum wherein the two compounds are not in the same layer, with a reasonable expectation of

success, as doing so is taught by '385 as one embodiment that affords an effective multi-layered tablet with tunable dosage strength.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618